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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MENON, KRISHNAN S

ART UNIT PAPER NUMBER

1723

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,505

Applicant(s)

WONG, RAYMOND J.

Examiner

Krishnan S Menon

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-38 and 50-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-38, and 50-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-11, 13-38, and 50-61 are pending.

Election/Restrictions

Applicant's election with traverse of claims of Group II, 50-56, in Paper of 10/15/03 is acknowledged. The traversal is on the ground(s) that: no grounds given. This is not found persuasive because there are no grounds for traversal given. Re applicant's request to rejoin Group I (examiner believes the request for group II is a typo, and assume it is group I): process claims would be allowable if product claims are found allowable and if the process claims contain all the limitations or are dependent on the product claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-9,11,13-16,19-25,29-38,and 50-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of Applicant's own disclosure of prior art.

Polak teaches a sorbent comprising at least sodium zirconium carbonate (see col 5 line 68 – col 6 line 11) as in claims 1 and 11. Re the newly added limitation of the layers comprising SZC, or grp IVB carbonate (claim 11) in a cartridge, Polak teaches a capsule and do not disclose layers comprising SZC. Applicant's disclosure of prior art REDY® teaches sorbents in layers in a cartridge (specification pages 5-8 and figure 1 and 8). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of applicant's disclosure of prior art REDY® in the teaching of Polak to have absorbent SZC or grp IVB carbonate in layer form for removal of phosphates from uremic patients as taught by REDY® and Polak, and in a cartridge form for easy replacement.

Claim 2: Re the newly amended limitation, 'one of said layers consisting essentially of sodium zirconium carbonate', Polak teaches SZC as PO₄ absorber, but contains additional materials like Mg-Phosphate. REDY® teaches use of "HZO-Ac" as a separate layer for PO₄ absorption (specification page 5). It would be obvious to one of ordinary skill in the art at the time of invention to use SZC as taught by Polak as a separate layer in the REDY® cartridge for PO₄ absorption because the two are equivalent and performs the identical function specified in the claim (as taught by Polak) in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000)

Claims 3 and 13 add the further limitation of ZrP/group IVB metal phosphate, and claims 4 and 13 have ZrP as a layer as taught by REDY. It would be obvious to one of

ordinary skill in the art at the time of invention to use the teaching of REDY in the teaching of Polak (587) as the “zirconium phosphate or its progeny” for purifying the spent dialysate as taught by Polak (col 5 line 60-col 6 line 56).

Claim 5 adds the molecular composition of ZrP, and claim 6 adds the characteristics of ZrP (material property).

Claims 7 and 8 add limits on residual sulfate and chloride in ZrP (material property). Claim 9, pH of ZrP is a material property.

Claim 14 adds alumina, alumina supported urease, granular activated carbon, or combination thereof, with claim 15 adding these in layers (taught by REDY).

Claim 16 adds the order of the layers as taught by REDY except for the position of the granular activated carbon layer (applicant admits that it could be in any order on page 21 lines 22-23).

Claim 19: The composition of sodium zirconium carbonate is as given in col 6 lines 1-9, except for the LOD of 30-40%, which is due to water loss. However, water loss from drying sodium zirconium carbonate is an inherent material property.

Claim 20: Polak does not specify if the sodium zirconium carbonate satisfies the ANSI/AAMI standard. However, it would be obvious to one of ordinary skill in the art at the time of invention that the material being the same, it would satisfy such a requirement.

Claim 21: The sodium zirconium carbonate would satisfy the properties listed, being the same material – material properties.

Claims 22 adds ZrO and Claim 23 has ZrO in acetate form (taught by REDY).

Claims 29- 31: the quantity of the sodium zirconium carbonate, ZrP, and other components in instant claims is a design/optimization issue. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).

Claim 32 and 36 add immobilized enzyme (Urease in alumina), ion exchange materials (sodium zirconium phosphate), and adsorbent for creatinine (activated carbon), etc, all taught by REDY.

Claim 33 and 37 add chlorine removal material (activated carbon), Claims 34 and 35 add materials in layer form (see fig 1, REDY).

Claim 38 has the added limitation of two or more layers of the absorbents in the cartridge. Polak does not teach how the absorbents are structured in the cartridge, but REDY® teaches several layers. It would be obvious to one of ordinary skill in the art at the time of invention to have the absorbents in separately layered structure in the cartridge as a means for structuring the cartridge for improved performance as taught by REDY®.

Claim 50: Polak in view of REDY® also teaches an apparatus for conducting dialysis wherein the sorbent cartridge is in fluid communication with a dialyzer.

Claim 51: the dialysis fluid could be spent hemo-dialysis fluid (Polak – abstract)

Claims 52, 54 and 57: The spent fluid could be restored to the original Na⁺ and HCO₃⁻ content (abstract of Polak, and REDY®)

Claim 53: The apparatus could be in blood communication with a patient (see REDY®)

Claim 55 and 56: peritoneal dialysis (See Polak fig, col 5 lines 60-68, and the fig, col 2 lines 25-40 and claim 8 of the incorporated ref).

Claims 58 and 59 add the functional limitation of restoring the levels of sodium and bicarbonate in the dialysate to the fresh dialysate levels [functional limitation: While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).]

Re claims 24 and 25, claim 24 has ratio of ZrO/sodium zirconium carbonate as 1:1 and claim 25 has them blended together. REDY teaches ZrO for removal of phosphate and heavy metals (fig 8 of spec), sodium zirconium carbonate is for the removal of phosphates (Polak). It would be obvious to one of ordinary skill in the art at the time of invention that these two would be put together, since they are for similar functions and one would blend them together, since Polak does not teach any specific

the structure of the carbonate in the cartridge. Determining the ratio of the two would be only an optimization [In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Aller, 42 CCPA 824, 220 F.2d 454, 105 USPQ 233 (1955).].

Re the newly added claims 60 and 61, the location of the SZC layer is further away from the ZrP layer, which is taught by REDY® (see fig 1 of spec), since it is already established that the SZC layer is equivalent to the HZO-Ac layer of REDY®.

2. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of applicant's admitted prior art (REDY) as in claim 1 above and further in view of Potts (US 5,234,603).

Claims 26-28 adds the further limitations of basic zirconium carbonate, its composition, and purity, respectively, which Polak does not teach. Potts teach the basic zirconium carbonate (pH 9-14) for removal of heavy metals, transition metals and organic matter from wastewater (col 3 lines 55-61, col 4 lines 19-43), and that zirconium carbonate would hydrolyze to form the polymeric oxide chain (see structure at line 35, col 4 of Potts). It would be obvious to one of ordinary skill in the art at the time of invention to have the teaching of Potts in the teaching of Polak in view of REDY® for the removal of heavy metal and transition metal ions from the dialysate as taught by Potts.

3. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of applicant's own admitted prior art (REDY) as applied to claim 16 above, and further in view of Marantz et al (US 3,669,880).

Claims 17 and 18 add structural components like filter pads and diffuser. REDY teaches a filter pad (fig 1), but not the diffuser for flow distribution. Marantz teaches a flow distributor and filter pads (see figures 2,3). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Marantz in the teaching of Polak in view of REDY for the flow distribution and for preventing the breaking up and inter-mixing of particles in layers as taught by Marantz (col 2 lines 10-30).

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polak (587) in view of applicant's own admitted prior art (REDY) as applied to claim 3 above, and further in view of Tawil et al (US 4,025,608).

Polak (587) in view of applicant's own admitted prior art (REDY) teaches all the limitations of claim 3. Claim adds the further limitation of particle size to 30-40 microns for the ZRP particles, which Polak in view of REDY does not teach. Tawil teaches the particle size of ZRP (col 2 lines 54-59). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Tawil in the teaching of Polak in view of REDY for the particle size of ZrO for good flow distribution as taught by Tawil.

Response to Arguments

Applicant's arguments filed 10/15/03 have been fully considered but they are not persuasive.

In response to applicant's argument that Polak 'never teaches or suggests using a layered structure and never once teaches ZrP with SZC', please refer to the rejection again. Polak teaches ZrP as prior art, with specific references to the prior arts. Polak does not teach away from ZrP either: MGP is taught as alternate or improvement over ZrP. "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments" (In re *Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)). A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

In response to the argument re layered structure, Polak teaches layered structure as shown above. Also, having the material in a pouch does not make it any less layered.

In response to the arguments re the benefits of SZC (like correcting metabolic acidosis, buffering the solution, etc.), SZC is taught by Polak, the primary ref, and the properties of SZC are inherent. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art

cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant's argument in this regard is based on Polak "not teaching layered structure", which is not true because of the myriads of references Polak cites, which teach layered structure. As far as the "pouch" in Polak is concerned, Polak is using it only to show the effectiveness of the compounds in an experiment – see example IV.

In response to applicant's argument that Potts and Polak are not within the same filed of endeavor, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the two references are well within the filed of applicant's endeavor, because the Zr compounds are considered as ion exchange materials, as well as they have use in dialysis, as taught by the primary reference (see col 2 lines 32-43).

Arguments re the Marantz ref: mere argument that the cartridge used in Marantz would not work in Polak, without pointing out why it would not work, is not a reason for non-obviousness. Marantz ref is used to show the flow distributor, and there is nothing in Polak that would make it not work, simply because ZrP is replaced by MGP. Moreover, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Argument re Tawil ref that the ZrP is made by reacting a zirconium salt with a phosphoric acid (different process?) ..., wherein the zirconium salt is insoluble in water; and that the Examiner cannot simply substitute different particles and argue that the same size automatically can be used: ZrP, made by any process would still be ZrP, unless the applicant can show a significant difference in structure or chemical composition of the product made by the different processes. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner


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